**Albumin Reagent**

**Catalog #: 70125**

for use with the

**LIASYS-450 CLINICAL CHEMISTRY SYSTEM**

**INTENDED USE**
This reagent is intended for the in vitro quantitative determination of albumin in human serum.

**CLINICAL SIGNIFICANCE**
Observations of serum albumin level is useful as an aid in diagnosing disease states of the liver and kidneys. Moderate to large changes in the concentration of albumin have significant effects on the relative amounts of the bound and free concentrations of the ligands it carries: because free ligands are those that interact with tissue receptor sites and that can be excreted, albumin levels have important influences on the metabolism of endogenous substances such as calcium, bilirubin, and fatty acids and on the effects of drugs and hormones. Hypoalbuminemia is very common in many illnesses and results in most instances from one or more of the following factors: 1) impaired synthesis, 2) increased catabolism, 3) reduced absorption of amino acids, 4) altered distribution which may sequester large amounts of albumin in an extravascular compartment, 5) protein loss by way of urine or feces.

**METHODOLGY**
At a controlled pH, bromcresol green forms a colored complex with albumin. The intensity of color at 630 nm is directly proportional to albumin content. The instantaneous initial absorbance is obtained as suggested by Webster. The method used by LIASYS Albumin Reagent is based on that of Doumas

**Principle:**

BCG + Albumin (A = Absorbance)  
Controlled pH  
Green BCG/Albumin Complex

**REAGENT COMPOSITION**

<table>
<thead>
<tr>
<th>Active Ingredients</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brom cresol Green</td>
<td>0.25 mmol/L</td>
</tr>
<tr>
<td>Succinate Buffer</td>
<td>85 mmol/L</td>
</tr>
<tr>
<td>Surfactant</td>
<td>PH 4.20</td>
</tr>
</tbody>
</table>

**Precautions and Warnings:**
1. For in vitro diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spill, thoroughly wash affected areas with water. For further information, consult the LIASYS Albumin Reagent Material Safety Data Sheet.
3. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
4. Do not use the reagent after the expiration date printed on the kit.

**REAGENT PREPARATION**
Reagent is supplied ready to use.

**STABILITY AND STORAGE**
When stored at 2-25°C, the reagent is stable until the expiration date stated on the label.

**REAGENT DETERIORATION**
The reagent should not be used if:
1. The reagent is turbid.
2. The reagent fails to meet stated parameters of performance.

**SPECIMEN COLLECTION AND HANDLING**
Collection: No special preparation of the patient is necessary and sample preservatives are not required.

**Sample Type:** Serum is the recommended specimen. Collect blood into the appropriate sample tube by venipuncture.

**Storage:** Albumin in serum is stable for one month at 2-8°C.

**INTERFERENCES**
Studies to determine the level of interference for hemoglobin, bilirubin, and lipemia were carried out, the following results were obtained:

**Hemoglobin:** No significant interference (±10%) from hemoglobin up to 200 mg/dL.

**Bilirubin:** No significant interference (±10%) from bilirubin up to 15.5 mg/dL.

**Lipemia:** No significant interference (±10%) from lipemia up to 527.0 mg/dL measured as triglycerides.

A number of drugs and substances may affect the accuracy of Albumin. See Young, et al.

**ASSAY PROCEDURE**

**System Parameters**

<table>
<thead>
<tr>
<th><strong>Albumin</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>TEMPERATURE: 37°C</td>
</tr>
<tr>
<td>WAVELENGTH: 630 nm</td>
</tr>
<tr>
<td>ASSAY TYPE: Endpoint</td>
</tr>
<tr>
<td>DIRECTION: Increase</td>
</tr>
<tr>
<td>SAMPLE / RGT RATIO: 1 : 100</td>
</tr>
<tr>
<td>e.g. Sample Vol: 0.005 mL (5µL)</td>
</tr>
<tr>
<td>Reagent Vol: 0.5 mL (500µL)</td>
</tr>
<tr>
<td>INCUBATION: less than 90 seconds</td>
</tr>
</tbody>
</table>

**Procedure Notes:**
1. The temperature of the reaction is not critical, however the temperature should be held constant.
2. Unit Conversion: g/dL x 10 = g/L

**Calculations:**

\[
\text{A patient} \times \frac{\text{Concentration of standard (g/dL)}}{\text{A standard}} = \text{Albumin (g/dL)}
\]

**Example:**

\[
\text{A patient} = 0.200 \\
\text{A (standard)} = 0.190 \\
\text{Concentration of standard = 3.5 g/dL}.
\]

\[
0.200 \times 3.5 = 3.68 \text{ g/dL Albumin}
\]

**Limitations**
Samples with values exceeding linearity should be diluted 1:1 with saline and re-run. The final answer should be multiplied by two.

**CALIBRATION**
Use an aqueous Albumin standard or an appropriate serum calibrator.

**QUALITY CONTROL**
The integrity of the reagent should be monitored by use of a two level control with known Albumin values.

**EXPECTED VALUE**

**Method:**
When run as recommended the assay is linear from 0.0 to 6.0 g/dL

**Precision:**

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (g/dL)</td>
<td>1.6</td>
<td>3.0</td>
</tr>
<tr>
<td>S.D. (g/dL)</td>
<td>0.06</td>
<td>0.05</td>
</tr>
<tr>
<td>C.V. (%)</td>
<td>3.8</td>
<td>1.7</td>
</tr>
</tbody>
</table>

**Sensitivity / Limit of Detection:**
A calibration factor of approximately 6.3301 was obtained, which is equivalent to a sensitivity of 0.158 µmol/L per g/dL.

The lower Limit of Detection was found to be 0.0 g/dL.

**REFERENCES**
2. Webster D: 177. The Immediate Reaction between Bromcresol Green and Serum as a Measure of Albumin Content. Clin Chem 23:663

**Manufactured for:**

AMS Diagnostics

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